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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,188	09/17/2003	Emiliano Ghinelli	EMIL-001XX	5560

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,188	GHINELLI, EMILIANO	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-9,13-19,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending.

Response to Amendment

Applicant's amendment and response filed on Mar. 22, 2007 has been received and entered into the case.

Claims 20-26 are newly added and claims 1-9, 13-19, 25 and 26 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 10-12 and 20-24 have been considered on the merits. All arguments have been fully considered.

The claim rejections under 35 U.S.C.§102(b) and 103(a) are withdrawn due to the amendment.

Applicant's arguments with respect to claims 10-12 have been considered but are moot in view of the new ground(s) of rejection.

The declaration under 37 CFR 1.132 filed on Mar. 22, 2007 is sufficient to overcome the rejection of claims 10-12 based upon Wang et al. However, due to the amendment and subsequent withdrawal of the claim rejection based on Wang et al., the declaration is moot in view of the new ground of rejection.

Drawings

The drawings were received on Mar. 22, 2007. These drawings are acceptable.

Specification

The amendment made on the title of the current application is acknowledged and accepted.

Election/Restrictions

It is noted that applicant has not elected species from the group C required in the office action mailed on Aug. 18, 2006. However, the species election requirement on group C (type of pharmaceutically acceptable carrier) is withdrawn.

Claim Objections

Claims 22 and 24 are objected to because of the following informalities: The claims contain Markush type species. M.P.E.P. §2173.05(h) states "Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-12 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (KR2001098716A).

Claims 10-12 and 20-24 are drawn to a pharmaceutical composition comprising a mammalian amniotic membrane extract consisting essentially of a powdered form of a lyophilized mammalian amniotic membrane homogenate supernatant reconstituted in a pharmaceutically acceptable carrier, and the limitation to the mammalian amniotic membrane being from human, pig, cow or horse.

Kim et al. teach a pharmaceutical composition comprising human amniotic membrane extract made by the process steps of 1) freeze-drying (lyophilized) and pulverizing (powdered) amniotic membrane and 2) homogenizing the powdered amniotic membrane, followed by centrifugation to obtain homogenate supernatant (see p.3, paragraph 4 of translated version). Reconstitution step of the claimed invention would be inherently carried out in Kim et al's method step because the powdered amniotic membrane has to be reconstituted in a solution for homogenization and centrifugation.

Kim et al. also teach the pharmaceutical composition as a form of an ointment (see p.4), gel (see p.3), or eye drop (see p.4).

It would have been obvious for a person of ordinary skill in the art to modify the delivery formation of the amniotic membrane extract as an emulsion, a cream, a powder or a spray, because these different forms are commonly used in pharmaceutical industry as means for delivery of pharmaceutically active molecules such as the amniotic membrane extract. In addition, a person of ordinary skill in the art would recognize a bandage or medicinal contact lens would be additional means for delivery of such molecules.

Kim et al. do not particularly teach the amniotic membrane extract being powdered form of lyophilized amniotic membrane homogenate supernatant. That is homogenization and centrifugation first and followed by lyophilization of amniotic membrane. Rather the method steps disclosed in Kim et al. teach freeze-drying first followed by homogenization and centrifugation. However, the steps of Kim et al. would be considered to produce structurally same amniotic membrane extract as the current application. This is particularly because the key process step employed by the instant invention is collecting homogenate supernatant, and Kim's reference teaches the same process step to obtain amniotic membrane. Therefore, although the process steps are carried out in different order in Kim's reference, the steps are considered the same as the claimed invention.

M.P.E.P. § 2144 recites, "The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or

impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law...If the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court." In *In re Burhans, 154 F.2d 690, 69 USPQ 330* (CCPA 1946), the court found that selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. In *In re Gibson, 39 F.2d 975, 5 USPQ 230* (CCPA 1930), the court found that selection of any order of mixing ingredients is *prima facie* obvious.

Therefore, the examiner takes the position that the pharmaceutical composition of Kim et al. is the same as the claimed invention unless applicant provides clear evidence that the reference's amniotic membrane extract is structurally different from the instant application.

Although Kim et al. do not particularly teach the source of amniotic membrane being pig, cow or horse, it would have been obvious for a person of ordinary skill in the art to select any mammalian source of amniotic membrane to treat problems of corresponding animals.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made especially in the absence of evidence to the contrary.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (supra) in view of Carlsson et al. (US 6,117,857).

Claims 11 and 12 are drawn to a limitation to the pharmaceutical carrier being ophthalmic solution, a gel, an ointment, an emulsion, a cream, a powder, a spray, a bandage or contact lens.

Kim et al. teach a carrier such as a gel, an ointment, or eye drop (ophthalmic solution).

Although Kim et al. do not specifically teach other forms of pharmaceutically acceptable carriers (i.e. emulsion, cream or bandage), the carriers listed in the claims are recognized in the art as pharmaceutically acceptable carriers commonly used in pharmaceutical compositions as supported by Carlsson et al. (see column 7 lines 24-25), and therefore functional and mechanical equivalent of the ophthalmic solution or contact lens.

M.P.E.P. §2144.06 states "In re Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent

photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.)."

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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